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Barriers to optimizing inflammatory bowel disease care in the United States

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***Abstract*:** Significant progress in the management and modification of inflammatory bowel disease (IBD) has been made; however, significant barriers to the optimization of IBD care in the United States still exist. The majority of these barriers are constructed by insurance carriers and the integration of market pressures into healthcare decision-making. In this review, we highlight the barriers to IBD care optimization within the context of the US insurance system and review current and proposed solutions.

Keywords: barriers, inflammatory bowel disease, insurance

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Introduction

Inflammatory bowel diseases (IBD) encompass Crohn's disease (CD) and ulcerative colitis (UC) and affect approximately 3 million Americans, with a peak age of onset between 15 and 30 years.[1] IBD are chronic, progressive conditions characterized by periods of relapse and remission. The goals of IBD management focus on clinical and endoscopic remission as a means to prevent disease progression. Increasing evidence has noted that earlier initiation of biologic therapy in patients with moderate-to-severe disease achieves quicker and higher rates of remission which reduces hospitalization and surgery rates.[2,3] As such, the IBD treatment paradigm has shifted from a conventional 'step-up' approach that requires failure of corticosteroids, mesalamine, and thiopurines before biologic initiation to early effective therapy, which often means prompt initiation of biologics. This shift to first-line therapy with biologics can be seen in the clinical practice guidelines for both UC[4] and CD.[5]

Despite progress in disease management and modification, there are still significant barriers to the optimization of IBD care in the United States. The majority of these barriers are constructed by insurance carriers and the integration of market pressures into healthcare decision-making. In this review, we will highlight the barriers to IBD care optimization within the context of the US insurance system and review current and proposed solutions.

Architecture of care in the United States

There are two types of health insurance in the United States: (1) commercial insurance which is purchased from large payer companies and provided by employers, typically regarded as private insurance and (2) public insurance which is provided by the government but often administered by private insurance companies. According to 2020 census data, approximately 90% of people in the United States have health insurance coverage, 66.5% of which is commercial and 34.8% of which is public.[6] Nearly half of patients on Medicare, a public plan for primarily those 65 years or older, use a combination of public and private insurance by enrolling in private Medicare Advantage plans.[7] When assessing 2006–2019 Medicare and Medicare Advantage billing practices, the coding intensity has rapidly risen year-over-year in the Medicare Advantage compared to traditional Medicare; this translates to hundreds of billions of dollars in spending in excess of traditional Medicare.[8]

Hospitals are more commonly not-for-profit, with only 20% in the United States in 2020 run by investors. However, nonprofit hospitals can be further divided into 'private nonprofit' hospitals, which make up three-quarters of nonprofits, and

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public hospitals that are owned by state or local governments.[9] Private nonprofit hospitals can, in fact, be highly profitable. The value of the nonprofit tax-exempt status was estimated in 2011 at 24.6 billion with an estimated 74% of nonprofit hospitals providing community benefits in equal measure to their tax benefit.[10] Some of these profits appear in compensation packages for executives at nonprofit hospitals, which have risen rapidly, increasing from $1.6 to 3.1 million, or by 93%, from 2005 to 2015; over the same time, increases in wages for nurses, hospital workers, and pediatricians were 3%, 8%, and 15% respectively.[11] An emphasis on profits can lead hospital executives to bloat prices,[12] facilitate mergers that create hospital monopolies, and generally engender a culture of greed rather than compassion.[8,13]

Similarly, market pressures of for-profit insurance companies continue to be heavily integrated into healthcare decision-making. To control costs and maximize profits, insurance companies in the United States employ a number of different strategies. First, they require prior authorization for certain medications or procedures, an administratively burdensome process that results in delays in care.[14] Second, they provide a restricted drug formulary that specifies the list of prescription medications covered by the insurance plan. The formulary is determined by a pharmacy and therapeutics committee and reflects the current clinical judgment of their medical and pharmacy staff.[15] Medications not on formulary are typically denied and require a multilevel appeal process to be approved that includes peer-to-peer reviews, letters of medical necessity, and external reviews by state governments. Third, they implement patient cost-sharing or 'co-pays' as a way to directly reduce the amount insurance companies pay for medical care and indirectly reduce the amount of medical care patients may seek. These methods, which have numerous negative effects at the patient level that we will discuss below, are very profitable for investors. In 2021, one of the largest companies, UnitedHealth Group, returned $5.3 billion in dividends to their shareholders and repurchased $5 billion in shares due to their record profits.[16]

Barriers to care for patients with IBD

Fail-first policies or step therapy

Despite the consensus shift in IBD management away from a 'step-up' approach as is evident in US gastroenterology societies' clinical practice guidelines,[4,5] the majority of insurance companies in the United States still require patients to try and fail lower cost medications such as corticosteroids, mesalamines, and thiopurines before approving biologics or small molecule therapies. In a review of 50 insurance policies, nearly all (98% for UC; 90% for CD) were inconsistent with the American Gastroenterological Association (AGA) guidelines and require stepwise drug failure before anti-tumor necrosis factor approval.[17] Furthermore, approximately 30% of policies require the failure of at least two drugs before biologic approval, adding another barrier to optimization of care and exposing patients unnecessarily to ineffective medications.[17] Although these policies may drive down medication-related costs, they only serve to drive up disease-related costs in the long term as delays in appropriate care lead to increased rates of surgery and hospitalization.[2]

In a pediatric study ($n = 190$), the prior authorization process was associated with a delay of 10.2 [95% confidence interval (CI): 8.2–12.3] days, which, in turn, led to a 24.6 (95% CI: 16.4–32.8)-day increase in time-to-biologic initiation.[18] A subsequent adult study of 1693 authorizations showed similar delays of a median 11 [interquartile range (IQR): 6–20] days, but the length of delay increased with each level of appeal that was required [first appeal: 29 (IQR: 17–48) days; second level appeal: 51 (IQR: 27–84) days; external review: 73 (IQR: 28–98) days].[19] A quality improvement initiative within 18 adult IBD providers aimed at improving time-to-biologic- and small-molecule administration found that the insurance approval process step was not improved and actually lengthened over time despite their shortening time to medication administration by 4 days through streamlined internal processes.[20] Within the pediatric study, they examined the impact of medication delays on IBD-related healthcare utilization within 6 months from the delay, and those who required prior authorization had a 13% (95% CI: 2.5–23.4) increase in healthcare utilization after adjusting for demographics and disease-severity characteristics.[18]

Tiers of medications

Biologics and small molecules are considered 'specialty drugs' according to many insurance plans, a designation that alters their coverage and

shifts costs to the patient. Increasingly, insurance companies have been implementing patient cost-sharing plans for specialty drugs, requiring patients to pay a percentage of the total cost which can be in excess of tens of thousands of dollars annually. While the introduction of biosimilars was meant to reduce costs, this benefit has been seen only marginally by patients.[21] When out-of-pocket costs for infliximab were examined from 2014 to 2018 in a nationwide database, IBM Marketscan, about a third of claims for both originator and biosimilar had out-of-pocket costs, and, when adjusting for patient characteristics and time, they did not find a difference in out-of-pocket costs between those on originator *versus* biosimilar.[22] Furthermore, these estimates do not take into account industry-supported patient assistance programs. These programs are, in some cases, not offered for biosimilars leading to increased out-of-pocket costs for the patient. As an example, in 2020, there was an estimated savings of $300 in out-of-pocket costs *per year* for a patient on biosimilar infliximab compared to originator[21]; however, if the patient's co-payment is $400 with the originator's patient assistance program reducing that co-payment to $5, then there is an out-of-pocket savings *every infusion* of $395 for the originator.

Food and Drug Administration approvals

Food and drug administration (FDA) approvals, as noted previously, are important in determinations of medical necessity and additions to preferred drug lists. FDA approvals are plagued by bureaucratic barriers, including costly monitoring, cumbersome data collection, and restrictive eligibility criteria.[23] FDA approvals are not only for the medication but also for the dose and interval recommended on the label. Time and again, patients with IBD have been shown to benefit from changes to doses and intervals of biologic therapies,[24–26] but, given the static label dose, denials often result from requests that fall outside the label. These denials can also recur throughout a patient's treatment course. In 2021, Aetna, a large insurance carrier in the United States, made a sweeping determination that all patients on infliximab were required to return to the label dose and an interval of 5 mg/kg every 8 weeks. This led to all patients being notified that they would be abruptly returned to label dosing risking subtherapeutic levels and immunogenicity for many who had been maintained on off-label dosing. A targeted effort from clinical societies led to the repeal of this dangerous policy,[27] but not before patients were stressed and providers were overwhelmed with the administrative burdens of combatting this broad decision.

FDA approvals for IBD medications for pediatric patients often lag a decade behind those for adult patients, typically due to issues with recruitment for research studies.[28,29] This results in initial insurance denial of medications for pediatric patients despite existing approval for adult patients, leading to days-to-weeks-long delays in care while providers submit letters of medical necessity. Along the same lines, a broader debate is brewing about the incorporation of real-world evidence into the paradigm of evidence-generation deemed acceptable for FDA approval – the future of IBD care is rooted in personalized medicine which requires detection of small effects in small target populations, at times making large randomized controlled trials untenable.[30] The FDA approval process needs to shift to minimize barriers to patients receiving effective treatments given its close ties with insurance authorization, and this can be accomplished, in part, by incorporating more real-world data.

Clinical guidelines

In addition to FDA approvals, insurance authorizations will often cite clinical guidelines to deny medications. Clinical guidelines can take years to develop, resulting in the potential for them to be out-of-date at publication or shortly thereafter. Current North American guidelines for adult IBD care date from 2018 to 2021, and the two most recent guidelines do not address all currently available medications.[4,31–33] This problem is additionally heightened in pediatrics where the last North American guidelines for pediatric IBD have not been updated in over a decade,[34] stemming in part from the lack of pediatric FDA approvals. Furthermore, insurance companies may not even reference the most up-to-date clinical guidelines, leading to recommendations that are no longer standard of care. This necessitates appeals or peer-to-peer phone calls to discuss the inappropriate guidelines that led to a denial, unnecessarily increasing the workload of providers and delaying care. Furthermore, these phone calls are commonly not with true peers as they

can be providers, running the gamut from medical doctors to pharmacists, who are not in the same specialty and are not familiar with the care of patients with IBD.[35]

Similar to medications, medical tests can also be deemed medically unnecessary by payers even when they are recommended in clinical guidelines. The two most common examples of this are fecal calprotectin for tight control monitoring and drug levels for therapeutic drug monitoring (TDM).[36] They are, in most instances, denied by insurance despite being recommended in the AGA and International Organization for the Study of IBD guidelines.[37,38] The decision to utilize these tests requires achieving a balance between the benefit of the test in optimizing IBD care and the risk of burdening the patient with out-of-pocket costs. In a survey of 403 US gastroenterologists, one-third of physicians reported that they would apply proactive TDM if barriers related to insurance and cost were removed, highlighting the impact insurance coverage has on practice patterns.[36]

Non-covered services

Comprehensive care for patients with IBD requires services that US insurance companies frequently do not cover. This can lead to financial strain for patients and worsen clinical outcomes. Three salient examples are mental health services, biofeedback, and medically necessary foods. Unfortunately, these are only a few of many cases of how non-covered or out-of-network services can serve as serious barriers to care for patients with IBD in the United States.

Psychological comorbidities are well described and common in IBD.[39] It has further been shown that early intervention, before psychological distress spirals out of control, can lead to improved outcomes.[40,41] Due to this, it is recommended to address mental health and make referrals for support during the routine IBD visit[42]; yet, a patient's ability to follow through on these recommendations is limited in the United States by scarcity and out-of-pocket expense. While the Affordable Care Act (ACA) extended the insurance plans that needed to comply with the federal parity requirement for treatment of mental health conditions,[43] co-payments, and in-network requirements maintain strict conditions that present barriers for patient access. Psychiatrists participate significantly less than other providers in insurance networks, making it nearly impossible to find an in-network physician and often rendering care partially or completely not covered.[44] Thus, lack of access to mental health services is a prominent road block in achieving optimal IBD care, which includes holistically maximizing the well-being of the patient.

Biofeedback can help anorectal disorders in patients with IBD.[45] Fecal incontinence is debilitating and embarrassing, and biofeedback can lead to a patient's recovery of continence and confidence. However, it requires numerous sessions, and facilities offering it frequently are not in-network with insurance plans, leading to further out-of-pocket expenses and barriers to care.

Medically necessary foods are costly; for example, exclusive enteral nutrition may cost thousands of dollars just for the weeks of induction therapy. Yet, medical foods are commonly not covered by payers unless they are administered *via* a feeding tube in the United States, and this is often unnecessary for patients with IBD. The Medical Nutrition Equity Act (HR3783/S2013), introduced into the House of Representatives in June 2021, seeks to introduce legislation to rectify this issue but is receiving low traction in the US Congress.[46] This theme of rising costs due to lack of insurance coverage can also be extended to nutritional counseling services and integrative medicine.

Employer-sponsored health insurance conflicts with medication authorizations

Employee-sponsored health insurance (ESI) is a common means of coverage in the United States,[47] but it is particularly cumbersome given the authorization process required for specialty therapies. A change in employer or the policy offered by an employer can necessitate repeat insurance authorization for an existing therapy, which can lead to delays in therapy and development of symptoms. Given the burden of authorization, patients may feel limited in their ability to change jobs and feel undue stress with employer-related changes in insurance.

Financial toxicity

Financial toxicity describes the impact of direct and indirect costs of a health issue that lead to

significant financial burdens for patients.[48] Medical debt is an easy example of this, and it is rife in the United States today; a Census Bureau analysis revealed that one in five households have medical debt.[49,50] One in eight citizens with debt owe more than $10,000, and, in 2021, the Consumer Financial Protection Bureau reported that 58% of debts in collection were medical debts.[51]

Financial toxicity is particularly burdensome for patients with IBD. A 2020 study reported that patients with IBD incurred more than twice the out-of-pocket costs compared to patients without IBD ($2213 *versus* $979 per-year reported costs).[52] A quarter of adults with IBD report experiencing financial hardship from medical bills, 1.6 times more likely compared to patients without IBD (odds ratio: 1.56; 95% CI: 1.21–2.02). This can lead to worse disease outcomes as one in six patients report cost-related medication nonadherence.[48] The type of health plan can intensify this; high-deductible health plans incentivize delays in obtaining health care that worsen disease outcomes and increase financial distress.[53]

While financial toxicity is high in low-, middle-, *and* high-income families,[48] social determinants of health can amplify the impact. One in eight patients with IBD has food insecurity and lacks social support; both of which are associated with higher financial toxicity.[48] In 2018, Walter *et al.* found that race and socioeconomic status were both independently associated with increased hospitalization, but these two variables were highly correlated.[54] A 2022 review on IBD health disparities tied to social determinants of health-recommended multilevel strategies to address these determinants to improve downstream outcomes.[55]

More difficult to quantify are indirect costs like absenteeism and presenteeism from work and school. A survey study of 563 US patients, evenly divided between CD and UC, found that these issues were common and increase with disease activity in both groups ($p < 0.0001$). They are also quite costly with yearly estimates of $4348–$7169 in remission to $24,283–$29,524 with moderate-to-severe activity for UC and CD, respectively.[56] As an illustration, assuming a patient is diagnosed with UC at age 24 with one initial year of disease activity at diagnosis followed by remission to age 65, this would sum to a total cost of nearly $200,000 not factoring in lost earned interest.

Life and disability insurance are key components of financial health. Unlike health insurance, there are no exclusions for pre-existing conditions. Patients with IBD are likely to face higher premiums for life insurance. In addition, underwriters for disability insurance may decline outright to cover patients with IBD or demand reductions in benefit periods or exclusions; these declinations may occur even in the setting of long-term remission.[57] This leaves patients with IBD without a crucial safety net for themselves and their families.

Obtaining disability insurance is not to be confused with qualifying as a disability under the American with Disabilities Act (ADA). Patients should know their rights under the ADA, which recognizes IBD as a disability. Recognition of their rights can allow for patients to advocate for reasonable accommodations that result in higher rates of employment[58] and is an important avenue to combat financial toxicity.

Financial toxicity strikes from many angles, and the summation of all of these factors leaves patients with IBD on rockier footing to face the high bills that occur in caring for their lifelong, chronic illness. When they cannot pay their bills, patients have been shown to forgo care with disastrous results,[48] making advocacy for addressing financial toxicity an important cornerstone of advancing IBD care in the United States.

Burnout and moral injury

Providers in the United States are undergoing unprecedented levels of burnout, which, in turn, can worsen the care they provide.[59] A survey of 2440 physicians in 2021 revealed that 63% of them had at least one manifestation of burnout.[60] A 2020 survey of pediatric gastroenterologists, which ended just before the COVID-19 pandemic, identified factors tied to burnout as 'increased patient load/demands, insufficient nursing support, EHR use, insufficient administrative staff, excessive on-call coverage, and more complex patients'.[61] In a large ($n = 20,665$, 34% organizational response rate) US healthcare worker study, *Coping with COVID*, one in five

physicians and two in five nurses reported intending to leave practice within 2 years.[62] Nurses and physicians have intertwined burnout as decreased nurse staffing can lead to increased physician workloads, which, in turn, is a predictor of a physician's intent to leave practice[62] and results in a feedback loop that deepens concern over the future of healthcare staffing.[63]

In early 2022, the US Surgeon General released a call for action in the advisory *Addressing Health Worker Burnout*,[64] and President Biden signed the Lorna Breen Health Care Provider Protection Act providing federal funding for mental health education and awareness for healthcare workers.[65] These larger actions as well as institutional actions tend to focus on encouraging changes made by individuals. However, individual resilience deficits are not thought to drive this issue, meaning those solutions do *not* address the systemic issues at the root of the matter, like the structure, organization, and culture of health care. The National Academy of Medicine published a 2019 consensus calling for a change to these systemic issues, but much work still needs to be done to accomplish the goals they laid out.[66]

It has, further, been suggested that burnout is the incorrect terminology and that moral injury is in fact the root cause of the phenomenon. Moral injury is defined as occurring when people 'perpetrate, bear witness to, or fail to prevent an act that transgresses [their] deeply held moral beliefs'.[67] Moral injury has been shown to correlate highly ($r = 0.57$) with burnout, further strengthening the idea that they are interrelated concepts.[68] As we have described, a health system rife with barriers and the potential to bankrupt patients can be fraught for providers advocating for quality care with the intention of holistically improving patients' lives.

The prior authorization process is a behemoth barrier and contributes significantly to moral injury. Over a third of physicians ($n = 1004$) in a survey by the American Medical Association (AMA) reported that prior authorizations led to serious adverse events for their patients.[69] The AMA Recovery Plan for America's Physicians[70] recognizes this and ranks it one of the five most pressing challenges facing US physicians today. As a result, the AMA and other medical societies have been advocating for the Safe Step Act (S464/HR 2163) to reform medication step therapy protocols embedded in prior authorizations. There are also grass roots advocacy campaigns at FixPriorAuth.org and social media (SoMe) hashtags like #FixPriorAuth and #RespectMyPrescription to bring broader social awareness to these issues.[69]

Disinformation and social media

While not unique to the United States, there has been a rapid erosion of trust in science and medicine, fueled by media and disinformation.[71] In the United States, people spend an estimated 7 h/day on the internet with just over 2 h of that devoted to SoMe.[72] In a survey of patients with IBD, a third of patients used SoMe to discuss subject matter related to their disease.[73] Another study, which examined patient perceptions of biologic use using natural language processing of SoMe, found that 55% of posts described negative experiences; this preponderance of negative stories leads to bias that may hamper building trust between physicians and patients.[74] Intentional disinformation, unintentional misinformation, and negativity bias on SoMe are all growing barriers to care in the United States. Individual providers have the power to fight back against this barrier by engaging in respectful discussion with patients weighing the evidence behind their recommendations compared to the anecdotes on SoMe[75]; providers can also engage in SoMe themselves to add firm and knowledgeable voices to cut through the cacophony.[76]

Breaking down barriers

The barriers we have described to care are complex, interwoven with systemic problems in health care and society at large, corporate greed, policy failings, provider exhaustion and moral injury, and other complicated issues. As such, solutions to these barriers require a multilevel approach, including federal, state, and local policy changes, insurance and Pharma reforms, organizational buy-in and advocacy, and provider-level initiatives.

Policy changes

One of the most significant changes to the healthcare architecture in the United States came in 2010 when the Patient Protection and ACA was

signed into law. Prior to the ACA, patients with IBD would be considered uninsurable if they applied for individual market coverage due to underwriting practices that existed in nearly all states, and patients lived in fear of losing ESI. The ACA implemented patient protections by covering pre-existing conditions and expanding dependent coverage from age 24 to 26, an important young adult period when IBD is often diagnosed. These protections are a significant advancement for patients with IBD.[43]

Since the ACA was enacted, uninsured rates have declined[77] and mortality rates have decreased.[78] More recently, the 21st Century Cures Act[79] and the No Surprises Act[80] joined the ACA in further reform. These Acts enacted numerous improvements including allowing patients to access health information more easily, granting physicians of complex patients the ability to bill for their time spent, and stopping insurance companied from sending patients surprise bills that can be financially devastating. Most recently, the Inflation Reduction Act of 2022 included reforms to allow the federal government to negotiate prices of medications starting in 2026.[81]

Patient-focused quality improvement programs

The emergence of nonprofit organizations and support groups in IBD has been a growing resource for patients and health professionals to combat barriers in IBD care. Patient-centered organizations and the gastroenterology community are focused on quality improvement to improve health outcomes and understand the burden of chronic illness on the lives of patients.[82] Despite progress, the gaps outlined in this article between evidence-based medicine and care delivery remain. To address these gaps, organizations including the Crohn's and Colitis Foundation (CCF) and the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) have implemented learning health systems as a model to improve subspeciality care.[83,84] Through various forms of outreach, including email registries, educational conferences, and social and fundraising events, these organizations have generated a community that is primed for collaboration and research.

Learning health systems were cultivated by the Institute of Medicine in 2007 as a model to generate and implement evidenced-based care and apply improvements to clinical practice and outcomes.[85] These quality care programs have successfully been implemented in other chronic illnesses, including adult rheumatoid arthritis with The Swedish Rheumatology Quality Registry.[86] In 2007, NASPGHAN and the American Board of Pediatrics co-sponsored the creation of a learning health network for pediatric patients with IBD, ImproveCareNow,[83] which, as of 2020, gathered data from 970 pediatric gastroenterologists caring for 30,400 pediatric patients with IBD from 106 member centers. Pediatric providers have been able to leverage this unique large-scale registry to perform projects aimed at enhancing quality of care for pediatric patients with IBD.[87] In 2016, the CCF launched IBD Qorus, its flagship quality of care program for adults with IBD.[88] By collaborating with other IBD centers across the United States, IBD Qorus will utilize the patient–physician relationship for shared decision-making based on best-known evidence and patient's preferences along with the collection of quality data to inform healthcare delivery, quality improvement, and research.[88]

Information gathered from learning health systems is summarized to generate new evidence for future practice. Partnerships between medical societies and patient-centered organizations have been pivotal in distributing guidelines to patients and health professionals. Educational conferences, including Digestive Disease Week and Crohn's and Colitis Congress, have sessions designed for patients to navigate information and receive suggestions on bringing together the health team for collaborative care.

Support for medical practices

As previously mentioned, the prior authorization process for necessary procedures and medications is not only a tremendous burden on medical practices, but also a barrier in delivering timely care to patients.[89] In 2015, the American College of Physicians launched its Patients Before Paperwork Initiative to bolster the patient–physician relationship by confronting practice burdens.[90] Strategies that have been put forward include calling on stakeholders (i.e. payers, government organizations, vendors) to provide impact statements for public review and comment, review and

revisit administrative tasks with goals to streamline them, and collaboration between professional societies and payers to provide transparency and delivery timely care to patients.[91] The AMA encourages patients and physicians to submit their prior authorization stories and sign onto their reform petition.[92] Beyond advocacy for policy reform, societies, such as CCF[93] and NASPGHAN,[94] provide customizable letters of medical necessity to use in the prior authorization process.

At the local level, individual practices can provide training to staff to navigate the challenging authorization process. A dedicated prior authorization staff member or team of staff members can also be invaluable to a medical practice and serve as a liaison between the payer and patient. In larger health systems, a centralized pharmacy can often assist with the authorization process as well, reducing the burden on the office staff. Finally, pharmaceutical companies can often assist with checking eligibility and providing medication for a period of time if there is a denial, if the patients approve of this pathway. Pediatric patients, however, cannot receive this assistance without an FDA approval in place, which again leaves them at a relative disadvantage.

IBD Home

An important aim of the ACA was to reinvigorate patient-centered medical homes by offering financial incentives through increased reimbursement.[43] A medical home is a system designed to coordinate patient care utilizing a multidisciplinary approach to improve clinical outcomes, reduce healthcare costs, and improve patient satisfaction in the acute, chronic, and preventative aspects of illness.[95] Given the rising cost in IBD and barriers to care, the concept of a Medical Home extended to subspecialties such as gastroenterology.[96] In an IBD Home model, the role of the gastroenterologist is that of a principal care provider who utilizes physician extenders, including nurse ambassadors, registered dieticians, behavioral health specialists, social workers, and health coaches to work closely with patients to improve health and outcomes. The IBD Home model places the patient at the center of the medical model and incorporates essential components, including team-based care, care coordination, outcomes, technology, and care access.[97] It further can remove barriers to obtaining previously non-covered services such as nutrition and mental health. Digital platforms have the potential to extend these benefits providing digital services and virtual visits to those who do not have access in-person to a medical home.[98,99]

Conclusion

The barriers to IBD care in the United States are many and although significant strides have been made by policy changes and advocacy from foundations, medical societies, healthcare workers, and patients, much work remains to be done (Figure 1). Access to care needs to be streamlined, quality of care standardized, and costs – particularly out-of-pocket – improved. Recognition of issues created by insurance companies that result in barriers to care allows for the development of important legislation for lasting solutions. By focusing on patient-centered models of care, which is supported by ACA, the IBD community can now work within restrictive insurance coverage of ancillary services by introducing multidisciplinary models for care.[43] Advocates and grassroots movements are actively making strides to bring attention to patient protection solutions, but some of these solutions, like those advocating for coverage of medical food, get stalled in Congress. Care should also be taken that proposed solutions may not bear out due to systemic issues, like the promise of reducing patient costs with biosimilars that did not in truth impact the patient's wallet due to the complexity of pharmacy benefits in the United States. Unfortunately, individual providers and practices are bearing much of the burden currently by spending significant resources in provider time and/or hiring non-provider staff members to navigate the red tape, and this stopgap solution, in turn, drives rising physician burnout and moral injury, which is unsustainable. IBD care holds so much promise with a rapidly enlarging armamentarium and increasing efforts to personalize care; however, if solutions to these logistic barriers are not developed alongside these scientific advances in care, outcomes in IBD may stagnate, and patients may suffer unnecessarily.

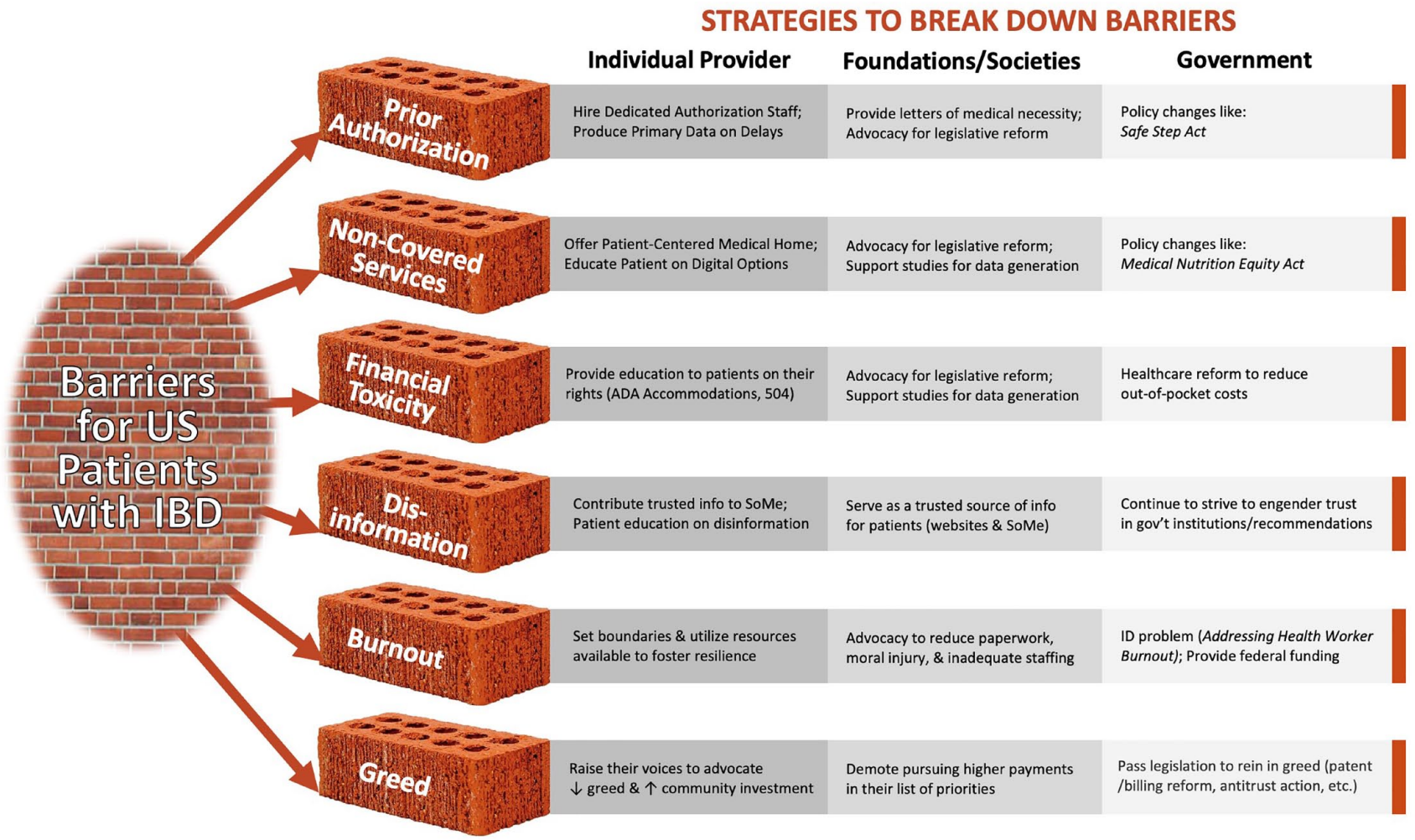

Figure 1. Strategies to break down barriers for patients with IBD in the United States.

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Author contribution(s)
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